



MEDICAL DEVICE MARKET & REGULATION IN TURKEY

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Health Transformation Program (HTP) IN TURKEY

Turkey has accomplished remarkable improvements in terms of health status in the last three decades, particularly after the implementation of the Health Transformation Program (HTP)

The healthcare system in Turkey is being developed under the 2003-2013 Health Transformation Program.

The purpose of this program is to increase the quality and efficiency of the healthcare system and enhance access to healthcare facilities with the introduction of a number of reforms.



TURKEY
HEALTH TRANSFORMATION PROGRAM



HEALTH SECTOR OVERVIEW IN TURKEY



Population of Turkey (2012) : 75million

Year	Number of Healthcare Facilities (Hospitals)
2002	1,156
2008	1,350
2012	1,483

Source: General Directorate of Health Services, 2012

Year	Number of Beds
2002	164,471
2008	183,200
2012	200,072

Source: General Directorate of Health Services, 2012

Year	Number of ICU Beds
2002	2,214
2008	13,965
2012	23,606

Source: General Directorate of Health Services, 2012

HEALTH SECTOR OVERVIEW IN TURKEY



	2002	2008	2012
MR	58	517	921
CT	323	759	1,142
Ultrasound	1,005	2,117	4,240
Doppler	681	1,095	2,463

Source: General Directorate of Health Services, 2012

<i>Number of reference to physicians</i>	2002	2010	2012
Primary Care	74,827,580	202,313,420	235,137,150
Secondary- tertiary levels of care (hospitals)	134,138,461	336,772,546	386,649,150
Total	208,966,049	539,085,967	621,786,297

ECONOMIC INDICATORS

Economic Data	2010	2011	2012	2013	CAGR
GDP (US\$bn)	729.1	772.6	787.1	865.9	3.5
Real growth (%)	9.1	8.8	2.2	4.4	n/a
Per capita (US\$)	,021.3	10,491.5	10,564.2	11,489.7	2.3
Health Expenditure (US\$bn)	48.7	51.3	54.0	58.5	5.7
Per capita (US\$)	668.8	697.0	724.2	776.2	4.5
Health expenditure % of GDP	6.7	6.6	6.9	6.8	2.1

Source: BMI Espicom, 2013

- GDP (gross domestic product) in 2013 \$865 B
- 2014-2018 annual increase of 3.7% expected to become \$1.179 B
- Inflation rate 7.4% (2013 - Central Bank)

HEALTHCARE EXPENDITURE

- 6.8% of GDP \approx \$60 B (\$776 per capita)

75% Public Sector \rightarrow SSI accounts for \approx 60%

\$45 B

\$585 per capita

25% Private Sector \rightarrow Out of pocket payments >50%

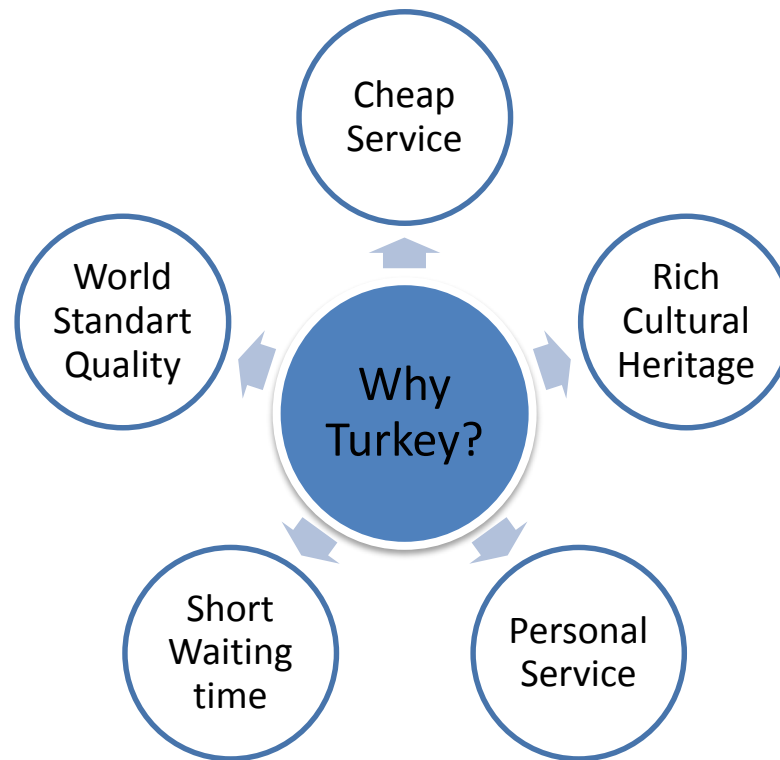
\$15 B

Private insurance \approx 10%

\$191 per capita

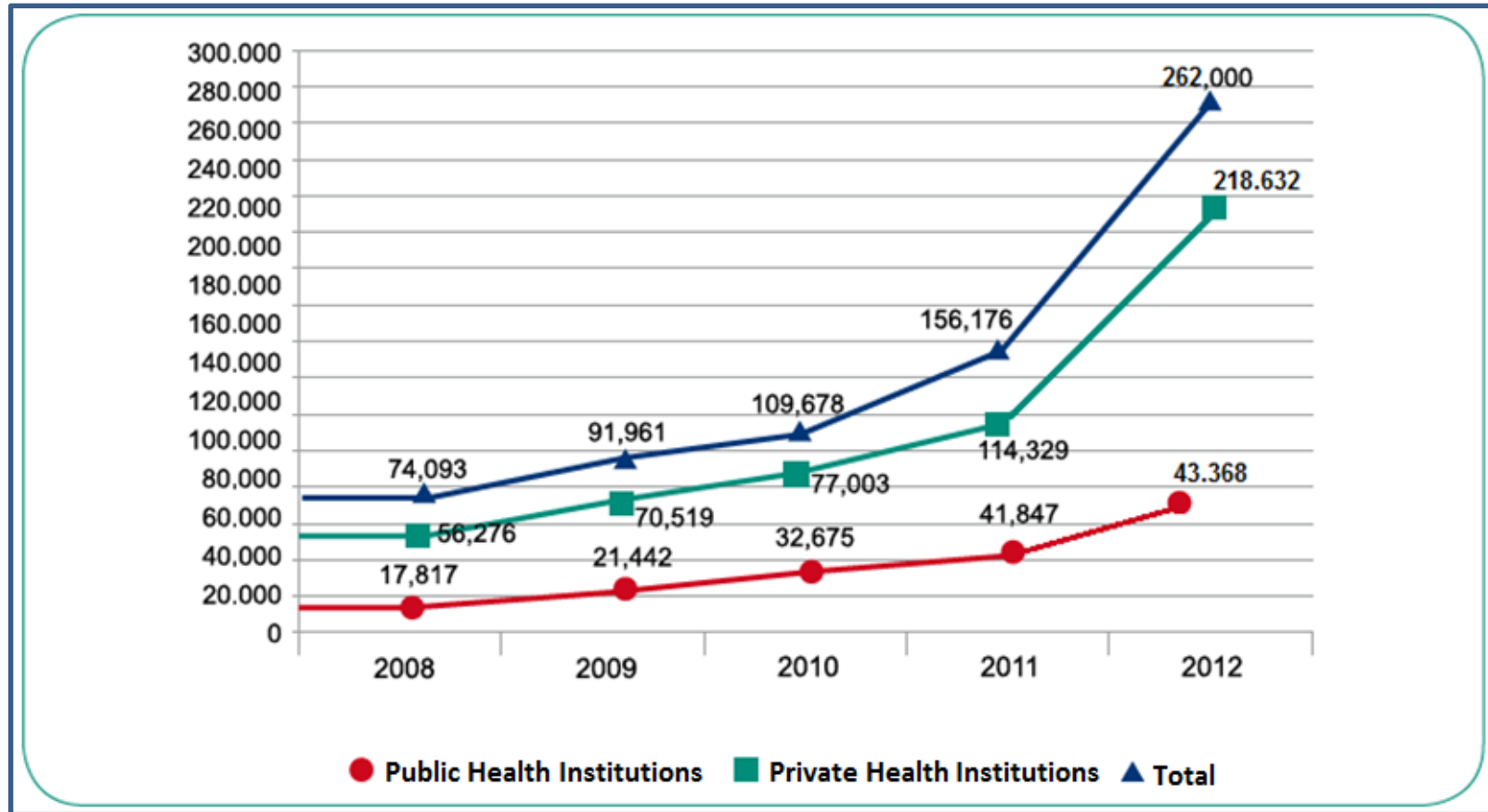
MEDICAL TOURISM

- Turkey is becoming an important player in health tourism (medical tourism, elderly tourism, disabled tourism and thermal wellness tourism).
- In 2010, Ministry of Health - Health Tourism Department was founded.



MEDICAL TOURISM

TOTAL NUMBER OF HEALTH TOURISTS

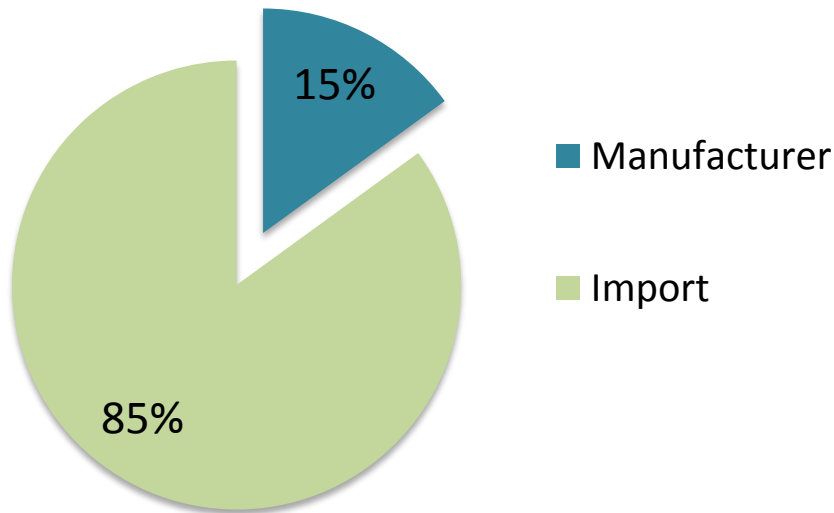


Medical Care for Health Tourists



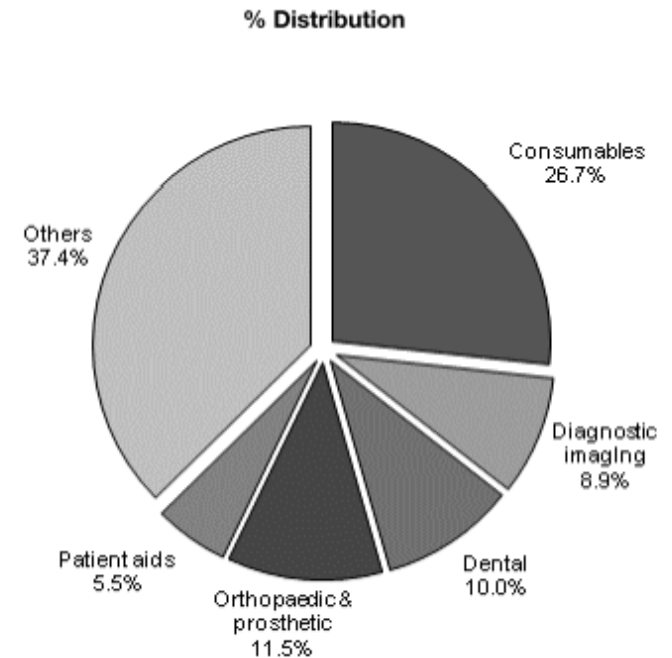
- All types of operations and surgeries and related crew
- Robotic Surgery
- Cyberknife
- All types of Imaging Systems such as CT, MR, etc.
- Transplantations (solid organs)
- Stemcell Transplantation and Bone Marrow Transplantation
- All types of Dental and Ophthalmic Services
- All types of Oncologic Treatment Methods

Medical Device Market in Turkey



➔ Turkey produces only a small amount of medical equipment and an estimated 85 percent is supplied from abroad.

Medical Device Exports By Product Area, 2012



Source: BMI Espicom, 2013

Medical Device Market in Turkey



Medical Device Market, Key Ratios, 2013

	2013
Market size, US\$mn	2,437.7
As % of total health expenditure	4.4
As % of GDP	0.3
As % of world market	0.7
Supplied by imports (%)	86.0
Projected CAGR (%)	8.5
Per capita (US\$)	32.3

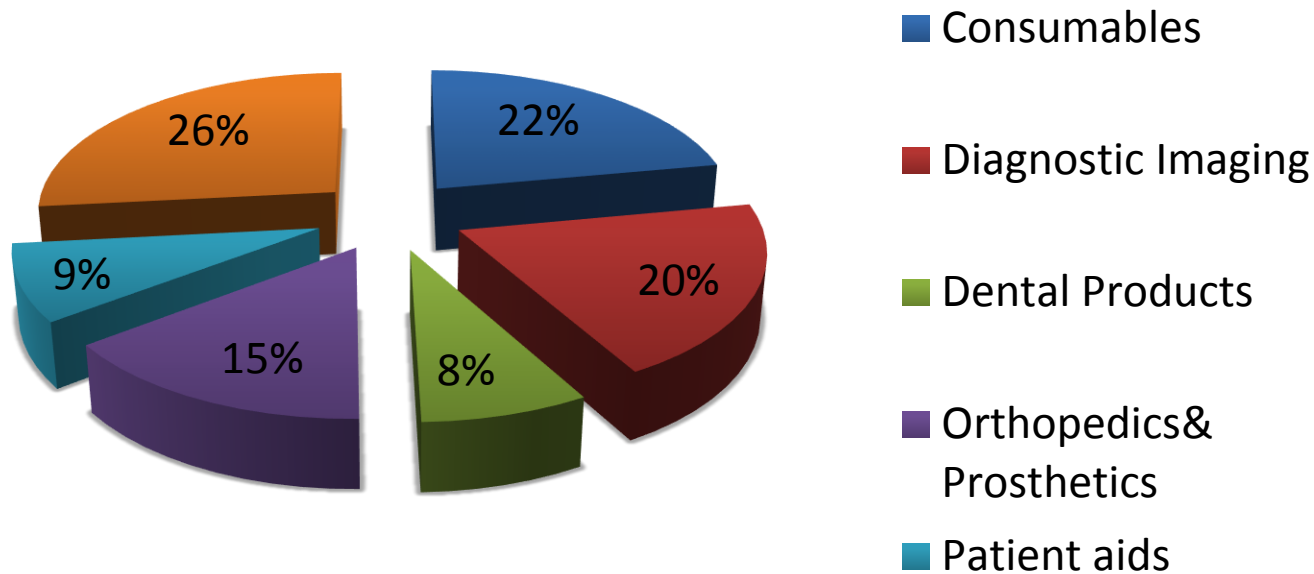
Source: BMI Espicom



➤ In 2013, the Turkish market for medical equipment and supplies is estimated at a US\$2,437.7MM, or US\$32 per capita.

➤ While the overall market size is large, per capita spending rates are somewhat average, similar to rates found in Mexico and Jordan.

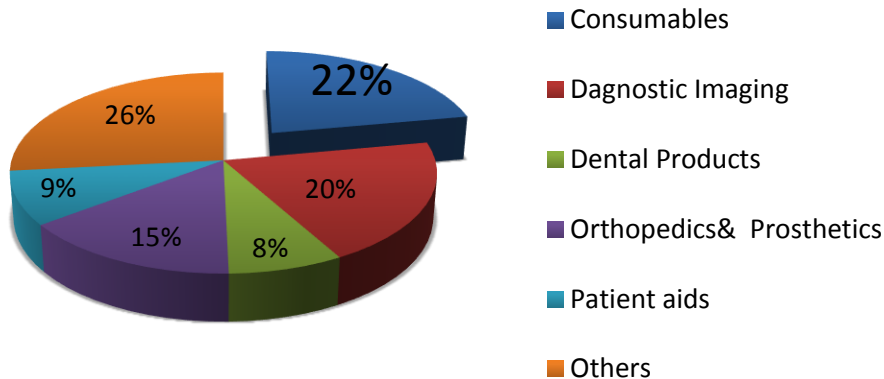
Medical Device Market in Turkey



	US\$m	As % of Total Market	Per Capita (US\$)	Local Currency mn	Per Capita (Local Currency)
Consumables	527.2	21.6	7.0	948.9	12.6
Diagnostic imaging	472.8	19.4	6.3	851.0	11.3
Dental products	185.7	7.6	2.5	334.3	4.4
Orthopaedics & prosthetics	357.3	14.7	4.7	643.1	8.5
Patient aids	210.2	8.6	2.8	378.4	5.0
Others	684.5	28.1	9.1	1,232.2	16.4

Source: BMI Espicom, 2013

Medical Device Market in Turkey - Consumables



- Bandages&dressings
- Suturing materials
- Syringes-needles-caths
- First aid boxes / ostomy products / surgical gloves



In 2013 makes up 21.6% of MDM

2013	\$ 527.2MM
2018(est)	\$ 848MM



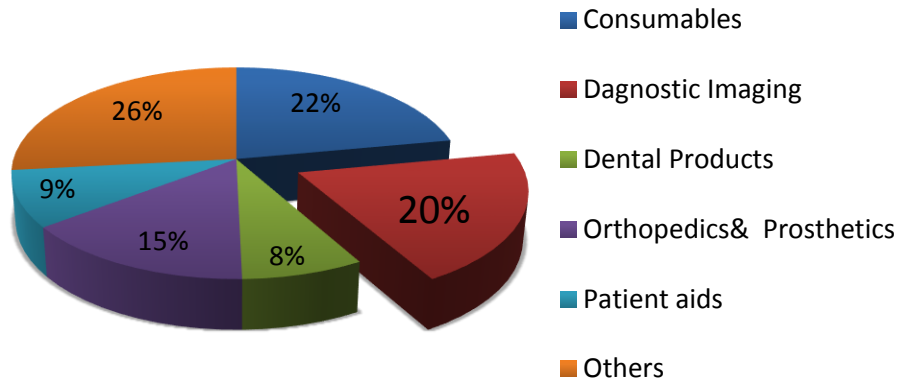
Annual growth expected 10%

Lowest	5.7%	suturing materials
Highest	12.2%	caths and cannulas



Leading Suppliers: USA, China, Malaysia

Medical Device Market in Turkey – Diagnostic Imaging



- Electrodiagnostic apparatus (ECHO,US, MRI, Sx)
- Radiation (CT, X-rays)
- Imaging parts and accessories (X-ray tubes, films, contrast media)

In 2013 makes up 19.4% of MDM

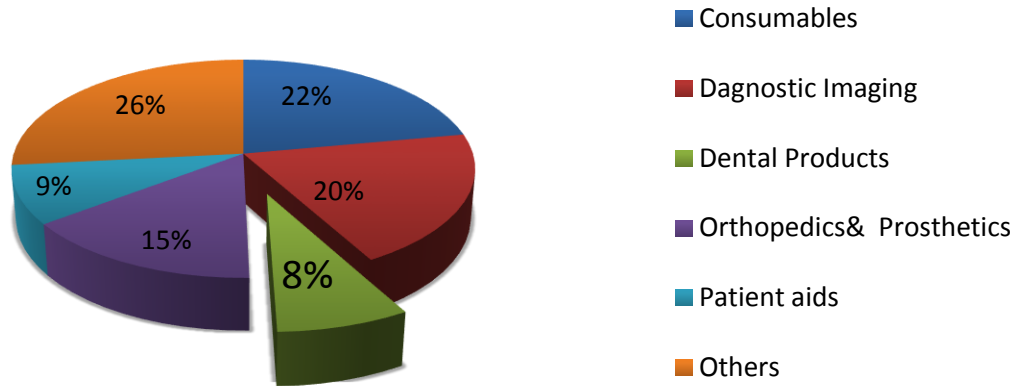
2013	\$ 472.8 MM
2018(est)	\$ 650.8 MM

Annual growth expected 6.6%

Lowest	2.2%	contrast media
Highest	9.7%	imaging part and acc.
	9.5%	electrodiagnostic apparatus

Leading Suppliers: USA, Germany

Medical Device Market in Turkey – Dental Products



•Capital equipment (dental drills, dental chairs/units/x-rays)
•Instruments and Supplies (dental cements, fittings, artificial teeth)



In 2013 makes up 7.6% of MDM

2013 \$ 185.7 MM

2018(est) \$ 298.1 MM



Annual growth expected 10%

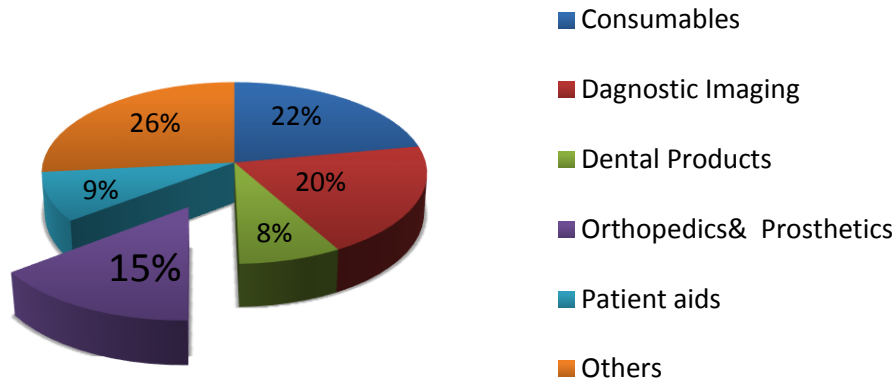
Lowest 7.8% dental chairs

Highest 11.2% artificial teeth



Leading Suppliers: USA, Germany, Japan

Medical Device Market in Turkey – Orthopedics & Prosthetics



- Fixation devices
- Artificial joints
- Other artificial body parts



In 2013 makes up 14.7% of MDM

2013	\$ 357.3 MM
2018(est)	\$ 545.4 MM



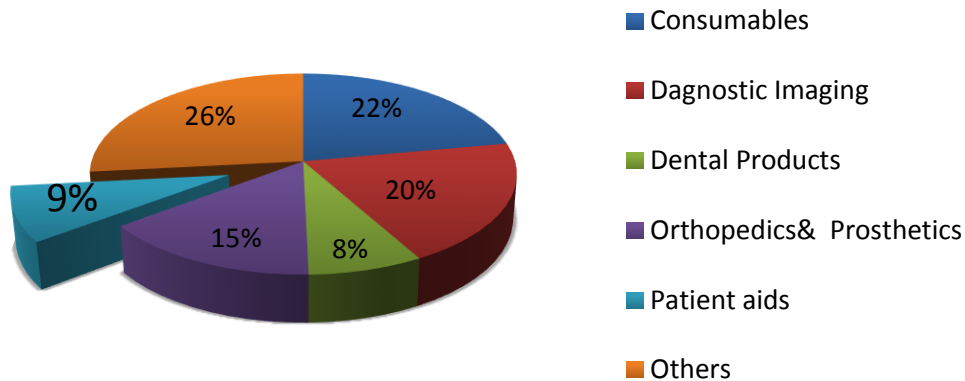
Annual growth expected 8.8%

Lowest	6.5% fixation devices
Highest	10.2% artificial body parts



Leading Suppliers: USA, Germany

Medical Device Market in Turkey – Patient Aids



- Portable Aids (hearing aids, cardiac pacemakers)
- Therapeutical appliances (respiratory, mechanotherapy)



In 2013 makes up 8.6% of MDM

2013	\$ 210.2 MM
2018(est)	\$ 308.6 MM



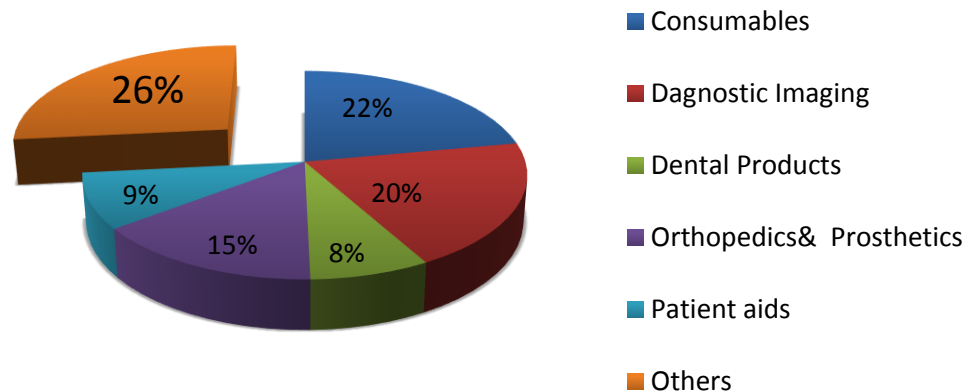
Annual growth expected 8.8%

Lowest	5%	mechanotherapy appliances
Highest	8.9%	hearing aids



Leading Suppliers: China

Medical Device Market in Turkey – Others



Leading Items	2013	2018	CAGR
Hospital furniture	62.5	95.4	8.8%
Dialysis appliances	55.7	80.5	9.4%
Ophthalmic inst.	51.8	75.7	7.9%
Transfusion app.	37.7	65.2	11.3%
Endoscopy apparatus	31.9	50.2	9.5%



In 2013 makes up 28.1 % of MDM

2013 \$ 684.5 MM

2018(est) \$ 1,020 MM



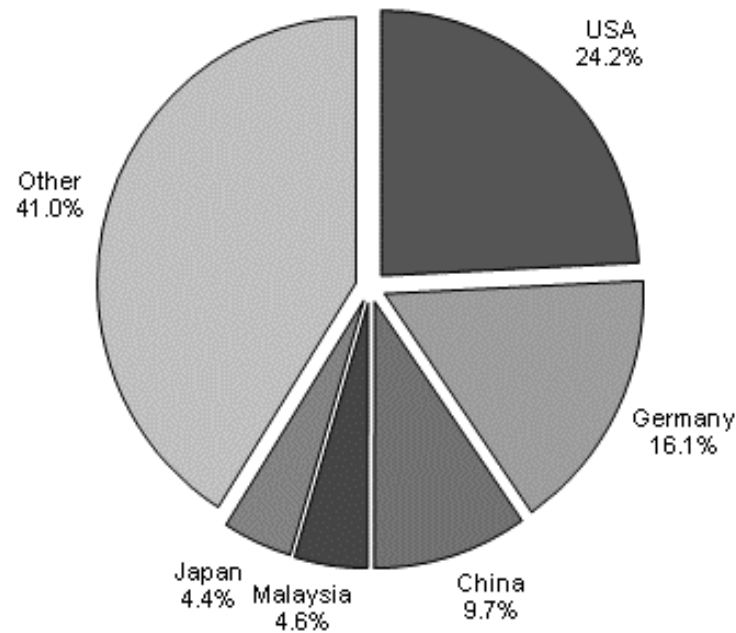
Annual growth expected 8.3%



Leading Suppliers: USA, Germany, China

Leading Medical Device Suppliers, 2012

% Distribution



	Country	2012	% of Total
1	USA	466,869	24.2
2	Germany	311,192	16.1
3	China	186,527	9.7
4	Malaysia	88,251	4.6

Source: BMI Espicom, 2013

Medical Device Market in Turkey



- 3/4 of healthcare expenditure is in the public sector .
- Development plans are made to speed up health development.
- Turkey represents a steadily growing medical device market and is ranked amongst the top 20 largest in the world in value terms.
- Consistent levels of public health expenditure.
- Falling morbidity and mortality rates are leading to older population that needs more sophisticated healthcare.



Medical Device Market in Turkey



- Multiple healthcare providers offer choice (governmental hospitals, university and research hospitals, private hospitals etc.)
- Although medical device export is rising annually, market is still heavily reliant on imports.
- Market regulations are in line with EU.



Medical Device Market Forecast



	2013
Market size, US\$mn	2,437.7
As % of total health expenditure	4.4
As % of GDP	0.3
As % of world market	0.7
Supplied by imports (%)	86.0
Projected CAGR (%)	8.5
Per capita (US\$)	32.3

➤ The prospects for the Turkish medical device market remain good; by strong imports, the expansion of healthcare facilities, coupled with rising health expenditure, should see the market grow at an attractive CAGR of 8.5% during the 2013-2018 forecast period.

Source: BMI Espicom, 2013

	Total (US\$mn)	Per Capita (US\$)
2013	2,437.7	32.3
2014	2,674.9	35.1
2015	2,932.9	38.1
2016	3,171.9	40.8
2017	3,412.3	43.4
2018	3,669.3	46.3

Source: BMI Espicom, 2013

Regulation of Medical Devices in Turkey



As part of Turkey's bid to join the EU, and customs union with the EU since 1996 ,national legislation regarding medical device regulation has been aligned with that of the EU, although that process is not yet complete.

As a result of this alignment, the regulatory environment in Turkey has become more complex and the processes are much more comprehensive than elsewhere in the Middle East.

Regulation of Medical Devices in Turkey



EU Harmonized Standards for Medical Devices

- Medical Device Regulation(93/42/EEC)
http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/index_en.htm
- Active Implantable Medical Device Regulation (90/385/EEC)
http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/implantable-medical-devices/index_en.htm
- In Vitro Medical Diagnosis Devices Regulation (98/79/EC)
http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/iv-diagnostic-medical-devices/index_en.htm

Medical Devices (MDD) 93/42/EEC

Covers the bulk of medical devices marketed in the EU

Examples: orthopedic implants, heart valves,
medical software

Active Implantable Medical Devices (AIMDD) 90/385/EEC

Covers devices that require external power sources
in order to function properly

Examples: pacemakers, implantable defibrillators

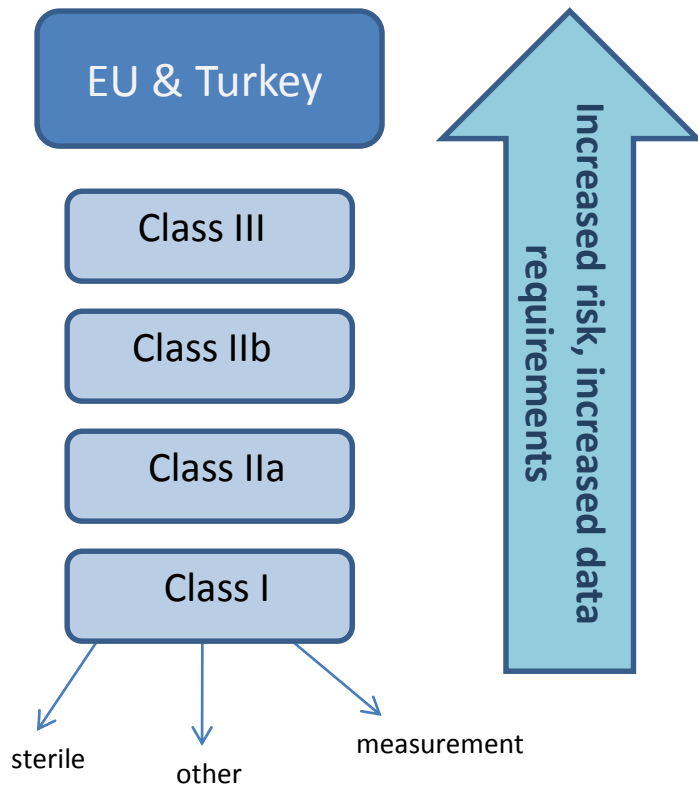
In Vitro Diagnostics (IVDD) 98/79/EC

Covers devices used for the examination of specimens
taken from the human body

Examples: pregnancy self-testing strips,
blood glucose self-testing strips

Regulation of Medical Devices in Turkey

- Classification of medical devices in Turkey is based on EU classification criteria.



Medical Device Directive 93/42/EEC Classification rules Annex IX.

Active Implantable Medical Devices (AIMDs)

Directive 90/385/EEC. AIMDs are regulated as high-risk devices.

***In Vitro* Diagnostics (IVDs) Directive 98/79/EC.** Most IVDs are regulated as low-risk devices, except for tests that underpin the safety of blood and blood products (blood group, HIV and hepatitis tests), where additional specific requirements equating to a high-risk category apply (List A, List B etc.)

Regulation of Medical Devices in Turkey

- Classification of medical devices in Turkey is based on EU classification criteria.

Risk classification	class I (low risk)	class IIa (low to medium risk)	class IIb (medium to high risk)	class III (high risk)
Examples	sticking plasters; corrective glasses	contact lenses; dental filling materials; tracheal tubes	X-ray machines; urethral stents	cardiovascular catheters; hip, shoulder and knee joint replacements; pacemakers

How to place a medical device in to the Turkish market?

Medical Devices in the scope of ;

- Medical Device Regulation(93/42/EEC)
- Active Implantable Medical Device Regulation (90/385/EEC)
- In Vitro Medical Diagnosis Devices Regulation (98/79/EC)

Should hold a CE sign and

Should have;

- Declaration of Conformity,
 - EC certification: given by a Notified Body authorized by EU (exceptions: class I-other for MDR, IVD-other for IVMDDDR),
 - Turkish translations of above documents.
-
- ✓ Only a notification/online registration is required to Turkish Medicines and Medical Devices National Databank to sell a medical device in Turkey.
 - ✓ Manufacturers should place the medical devices in the market under their own name. If located abroad, should designate an Authorized Representative/distributor in Turkey.



Turkish Medical Devices & Drugs National Databank (a.k.a TITUBB)

Medical Devices

World class Medical device database uniquely classified ...

- Online Registration System was launched in 2007.
- Turkish National Database also works with the reimbursement and procurement databases concurrently.

TITUBB Registration Process

- 1) Company Registration (Name, Tax Reg. No etc.)
- 2) Certificate Registration (Manuals, Catalogs etc.)
- 3) Product Registration (barcode, label name, risk classification, sterility status etc.)



NATIONAL DATABASE OF MEDICAL DEVICES IN TURKEY



Republic of Turkey
Ministry of Health
Medicine & Medical Devices Agency



Republic of Turkey
Medical Devices and
Drugs Databank



TC Sağlık Bakanlığı



SGK
SOSYAL GÜVENLİK KURUMU



KULLANICI GİRİŞİ

Sifre Yenile

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DATA BANK

TITUBB PORTAL

HISTORY

HELP

TURKÇE

International success

TITUBB has been added to International Social Security Assasiacion, ISSA, the best appliications database...

MORE

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System Usage	
Registered Users	61,481
Online Users	1,250

TITUBB 05.09.2013

Registered Company	3603
Local Manufacturer	1,333
Importer	2,270
Registered Medical Device	≈ 2,500,000
Manufactured Products	15%
Imported Medical Devices	85%

Reimbursement by SSI (Social Security Institution)

- In 2006, 3 separate social security (health insurance) organizations were merged to form SSI.
- Requires to be listed in the SUT-list (which the indications for each and every illness and/or health related condition is clearly identified.)
- Without the approval of Turkish Medicine & Medical Devices Agency, reimbursement application can not be initiated.
- Furthermore during the assessment of reimbursement, our agency provides scientific consultancy to SSI.

Procurement Process for Governmental Hospitals and Private Sector

- With the family practitioner scheme in place, medical equipment and devices are now purchased by family physicians working within primary care units. The equipment or devices are purchased through a competitive tendering process or are leased from the private sector.
- Medical devices and equipment for secondary and tertiary levels of care are purchased or leased through a public competitive tendering process.
- As the MoH procures a large number of medical devices and services for its facilities, the Medical Device Service Procurement Tenders Module has been established for detailed monitoring.

International Players in Turkish Market- Multinational Market Activities

Country	Operations
Boston Scientific	The company does not manufacture medical devices in the country but has a representative office in Istanbul.
Covidien	The company has a representative office, Covidien Saglik A.S. In Istanbul, but there is no manufacturing activity; products are imported.
Fresenius	Fresenius Medikal Hizmetler manufactures concentrates for haemodialysis. The head office is based in Istanbul. There are other sales offices located in Ankara, Izmir and Adana. Revenues amounted to US\$75.5mn in 2012. Fresenius operates 53 dialysis centres across Turkey, which have received investment in excess of EUR125mn.
General Electric	Since 2008, the company has had an international office in Istanbul covering what it terms the EAGM market (Central Asia, Middle East, Africa, Russia and Commonwealth of Independent States, or CIS). In June 2009, the company announced plans to invest in a new medical production plant in Ankara. No figures or further details of the investment were announced. The company said production will be geared mainly for export.
Johnson & Johnson	The company has a representative office, Johnson & Johnson Professional, in Istanbul. There is no known medical device production.
Medtronic	The company has no manufacturing plant or representative office in the country; products are imported.
Philips	Philips Healthcare Turkiye (Medikal Sistemler) is the main representative office located in Istanbul. There is no local manufacturing, products are imported.
Siemens	Siemens has a strong presence in Turkey. The head office is based in Istanbul, which is also the location for two manufacturing facilities, but these do not produce medical devices. The company has four regional offices in Bursa, Izmir, Ankara and Adana as well as sub-offices in Malatya, Trabzon, Kayseri, Gaziantep, Kocaeli, Konya, Eskisehir and Antalya. In 2012, Siemen signed a deal with Acibadem Hospital in Ankara to provide state-of-the-art medical equipment worth EUR9mn, as part of the hospital's renovation project. Siemens also completed projects for the MoH, delivering a CT package worth EUR5.4mn and an angiography/X-ray package worth EUR8.4mn. In addition, a key project was signed with the American Hospital in Istanbul to provide a SOMATOM Definition CT Dual Source. The project is valued at EUR2.1mn.
Smith & Nephew	The company has no manufacturing plant or representative office in the country; products are imported.
Stryker	The company has no manufacturing plant or representative office in the country; products are imported.

Thank you...

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